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P&G Case 8398

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of

Matthew T. Heisey et al.

:

: Confirmation No. 1681

Serial No. 09/759,965

:

: Group Art Unit: 1623

Filed: January 12, 2001

:

: Examiner: L.E. Crane

For LOW CARBOHYDRATE COMPOSITIONS, KITS THEREOF AND METHODS OF USE

REQUEST TO REINSTATE APPEAL UNDER 37 CFR § 1.193(b)(2)(ii)

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Applicants herein request that the Appeal of this case be reinstated. On May 5, 2004, the Examiner mailed an Official Action reopening prosecution of the Claims on Appeal. Applicants herein request reinstatement of the Appeal under 37 CFR § 1.193 (b)(2)(ii). A Supplemental Appeal Brief is submitted, in triplicate, herewith.

It is believed that no additional fees are due. But the Commissioner is hereby authorized to charge any necessary fee under 37 CFR §1.17, and any other necessary fees to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company, Patent Division. An additional copy of this Notice is enclosed for that purpose.

Respectfully submitted,

By

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Date: August 3, 2004

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USE

APPELLANT'S SUPPLEMENTAL BRIEF

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

On December 18, 2002 the Applicants appealed to the Board of Appeals the decision of the Examiner dated July 30, 2002 in which Claims 1-2, 4, 7-14, 16 and 19-50 were finally rejected. On October 8, 2002, Applicants submitted an Amendment After Final, in which Claims 10, 13-14, 16, 19-42 and 44-50 were cancelled. However, the remaining pending Claims were again rejected by the Examiner on October 22, 2002. As mentioned above, on December 18, 2002, an Appeal Brief was filed. On May 5, 2004, the Examiner mailed a Non-final Office Action in response to Appellants' Brief. Submitted herewith is a request under 37 CFR § 1.193(b)(2)(ii) to reinstate the present Appeal. This Supplemental Brief is submitted in support of that request. This Brief is being filed in triplicate.

NEW ISSUES

The Examiner presumably reopened prosecution in the present case to provide new grounds for rejection of the present claims. However, upon comparing the most recent office action, dated May 5, 2004, to the previous office action, dated July 30, 2002, Appellants are unable to see much novelty in the rejections, with the exception of an objection to the disclosure, which is addressed below. While the Examiner has arguably presented restructured rejections, and changed references, the substance of the rejections remains the same. Each objection and rejection is addressed below.

1. Objection to the Specification

The Examiner objects to Appellants' use of the phrase "all references cited herein are incorporated by reference," because the Examiner argues that this phrase is not in accordance with the requirement that all incorporations by reference point to the specific portions of the referenced document wherein the incorporated subject matter may be found. Appellants respectfully traverse this objection to the Claims.

Appellants respectfully assert that all matter herein incorporated by reference is non-essential material, and thus, the use of the phrase "all references cited herein are incorporated by reference," is proper. "Essential material" is defined in MPEP § 608.01(p) as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode. On the contrary, "non-essential" material is anything falling outside of the above definition. Non-essential material may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. patent applications, or (3) non-patent publications.

The presently referenced materials are non-essential in that, the present Specification itself describes the claimed invention, provides enabling disclosure, and satisfies the best mode requirement, without necessitating further review of the incorporated references. For example, on page 13 of the present Specification, naturally occurring sweeteners are discussed. The Specification lists "lo han guo" as an example of such a sweetener, and provides a reference to Fischer et al, U.S. Patent No. 5,433,965. It is not necessary to look to Fischer to find an example of a naturally occurring sweetener. Indeed, the sweetener, lo han guo is already disclosed. Therefore, the reference to Fischer simply provides the source of the information rather than the information itself, and is, for this reason, non-essential. Appellants respectfully assert that the same is true for the remaining references listed in the present Specification. Thus, the incorporation by reference is meant merely to provide the source of the described information, rather than the information itself. As such, Appellants respectfully assert that the phrase "all references cited herein are incorporated by reference" is proper and, therefore, request withdrawal of the objection to the disclosure.

2. The Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1, 2, 4, 7-9, 11, 12 and 43 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner objected to the use of the terms "cartilage," "aminosugars," and "glycosaminoglycans" in Claim 1, from which all other pending claims depend. More specifically, the Examiner states that the foregoing terms are "directed to a vast

array of compounds, only a few of which are known to have the desired beneficial effects claimed.” Additionally, in the May 5, 2004 Office Action, the Examiner further rejects Claims 1 and 2 under § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to make and/or use the invention. Appellants respectfully traverse these rejections.

The rejection of Claim 1 based on the use of the terms cartilage, aminosugars and glycosaminoglycans is purely repetitive of the previous rejection of Claim 1 under §112 and thus, is thoroughly addressed in the Appellants’ Brief.

The additional rejection of Claims 1 and 2 for a non-enabling disclosure is merely a reworded version of the previous rejection in that it ultimately stems from the use of the terms cartilage, aminosugars and glycosaminoglycans. Regardless, Appellants respectfully assert that one skilled in the art, reading the present Claims in light of the disclosure, would be enabled by the description contained therein. The Examiner admits that the state of the art, as well as the level of skill and predictability in the art, is high. See Office Action, Paper 18, page 4-5, paragraphs C-E. The Examiner asserts that this high level of skill and predictability is only true in regard to glucosamine, chondroitin, methylsulfonylmethane and S-adenosyl methionine, but not for what the Examiner refers to as the “generic” categories of cartilage, aminosugars and glycosaminoglycans. Appellants respectfully disagree. It is this very high level of skill and predictability, to which the Examiner refers, that enables a practitioner skilled in the art and coveys that the present inventors did indeed have possession of the claimed invention when the present application was filed. Consideration of the present claims in view of the present specification, and in light of the ordinary skill in the art, would allow a skilled practitioner to make and use the present invention. Thus, Appellants respectfully assert that the present Specification is definite under 35 U.S.C. § 112, based in part on the Examiner’s own Admissions.

3. The Rejection under 35 U.S.C § 103

The Examiner has rejected the present claims over a combination of nine references, only four of which are not discussed in the previously filed Appellants’ Brief. Namely, the Examiner has newly rejected the present Claims over Henderson, WO 98/48816 in view of Florio, U.S. Patent 5,840,715; Marino, U.S. Patent 5,922,692, Burger, U.S. Patent 5,843,919, Murad, U.S. Patent 5,804,594 and Herschler, U.S. Patent 5,071,878 and further in view of Applicants’ Admissions, pages 1, 2, 12 and 14, Vanderveen, “Vitamins and Other Nutrients,” Ch. 51, Remington’s Pharmaceutical Sciences, 18th Ed. and Swinyard, “Pharmaceutical Necessities,” Ch. 66, Remington’s Pharmaceutical Sciences, 18th Ed. The four newly cited references, Marino, Applicants’ Admissions, Vanderveen and Swinyard, are each addressed in turn.

Marino generally teaches the incorporation of glucosamine or chondroitin into dry foodstuffs to treat connective tissue disorders. At no time does Marino teach the formulation of these chondroprotective agents in a stable, low-carbohydrate beverage composition.

Applicants' Admissions generally teach that glucosamine, chondroitin and methylsulfonylmethane are useful in the treatment of arthritis, and sweeteners and natural sweeteners are known in the art. Appellants respectfully assert that this is hardly commensurate to teaching the stable, low carbohydrate chondroprotective compositions of the present invention.

Vanderveen generally discloses a vast list of ingredients that may be included in foodstuffs. However, Vanderveen fails to specifically teach the stable, low-carbohydrate chondroprotective beverages of the present invention.

Swinyard generally teaches various ingredients useful for pharmaceutical preparations. Again, Appellants respectfully assert that this laundry list of ingredients is not equivalent to the present stable, low-carbohydrate chondroprotective beverages taught herein. Rather, Swinyard, like Vanderveen, is merely a list of possible additives to compositions.

Appellants respectfully assert that, as indicated above, the newly cited art is merely cumulative of the art previously cited by the Examiner and, as such, adds nothing new to the rejection. The arguments provided by the Appellants in the Appeal Brief are equally applicable to these newly cited references. Therefore, as the new references do nothing, either alone or in combination with the other references, to remedy the deficiencies in the previously cited art, Appellants respectfully assert that the rejection under § 103 is improper and respectfully request withdrawal of such rejection.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company, assignee of Appellant's entire right, title, and interest in the invention at issue. A copy of this Assignment was recorded at the United States Patent and Trademark Office on August 15, 2002, at reel # 012990, frame # 0074.

RELATED APPEALS AND INTERFERENCES

Appellant, Appellant's undersigned legal representative and the Assignee are not aware of any pending appeals or interferences that would be directly affected by or have a bearing on the Board's decision in the subject Appeal.

STATUS OF CLAIMS

Claims 1, 2, 4, 7-9, 11, 12 and 43 are the subject of this appeal. No other claims are pending or allowed. Claims 3, 5, 6, 10, 13-42 and 44-50 were cancelled during prosecution.

Claims 1, 2, 4, 7-9, 11, 12 and 43 were finally rejected in an Office Action dated July 30, 2002. Appellants filed a Notice of Appeal on October 30, 2002, appealing from the final rejection. An Appeal Brief was filed on December 18, 2002. A Non-final Office Action was received on May 5, 2004.

Presently, Claims 1, 2, 4, 7-9, 11, 12 and 43 stand rejected as indefinite under 35 U.S.C. § 112, first paragraph, and as obvious under 35 U.S.C. § 103 (a). The Claims on Appeal are set forth in Appendix A.

STATUS OF AMENDMENTS

No amendments were filed or proposed after the receipt of the Office Action dated May 5, 2004, and it is believed that all previous amendments have been entered and considered.

SUMMARY OF THE INVENTION

The present invention relates to low-calorie chondroprotective beverage compositions, and kits thereof, for the treatment of joint health, bone health and anti-inflammation of joints *[page 1, line 2]*. As explained below, such compositions and kits are designed for individuals who are diabetic, overweight, obese, or generally concerned about caloric or sugar intake *[page 2, lines 5-9]*.

Osteoarthritis is a widespread, degenerative disease of the joints, cartilage, and other articular components *[page 1, lines 6-7]*. Osteoarthritis affects all ethnic groups worldwide *[page 1, line 7]*. Many treatments for osteoarthritis have been proposed, all resulting in varying degrees of success *[page 1, lines 9-10]*.

One osteoarthritis treatment that has been recently proposed is oral administration of chondroprotective agents such as glucosamine and / or chondroitin *[page 1, lines 11-12]*. Indeed, various commercial products are available in the marketplace, including nutritional supplements containing such agents and powders which may be formulated into beverage compositions immediately prior to use *[page 1, lines 14-16]*.

Typically, administration of such agents is designed to enhance proteoglycan through an increased concentration of glycosaminoglycans *[page 1, lines 17-18]*. Enhanced proteoglycan provides the framework for collagen and other joint components, as well as imparting flexibility, resiliency, and resistance to compression *[page 1, lines 18-20]*. Thus, these agents may be administered according to various methods to enhance the articular components or, at a minimum, inhibit the process of degradation *[page 1, lines 20-21]*.

Chondroprotective agents may be delivered in the form of compositions having high sugar content (e.g., fruit juices). It is well known in the art that the taste of glucosamine itself is quite unpleasant. Thus, added sugar is necessary to improve palatability and increase consumer

compliance when glucosamine is consumed in liquid form. *[page 2, lines 1-3]*. However, these highly sugared compositions are extremely caloric and can contribute to the elevation of blood glucose levels *[page 2, lines 3-4]*. These may be undesirable for the ordinary consumer, and may be particularly undesirable for those individuals who are overweight, obese, or even those who merely understand the importance of limiting caloric and sugar intake *[page 2, lines 4-7]*.

Additionally, the diabetic individual may be precluded from ingesting such highly sugared chondroprotective compositions due to their potential affect on systemic blood glucose levels *[page 2, lines 8-9]*. Ironically, however, the diabetic individual will often have the most critical need for these chondroprotective agents *[page 2, lines 11-12]*. This critical need is, in part, due to the excess weight gain typically experienced by the diabetic individual, which can lead to increased pressure on the joints, cartilage and other articular components, and ultimately osteoarthritis *[page 2, lines 12-14]*.

Moreover, it is well known to the skilled artisan that traditionally, chondroprotective beverages have been difficult to formulate due to stability problems, as indicated by the fact that most chondroprotective products take the form of capsule, tablets or powders mixed with water immediately prior to consumption. These delivery systems are flawed. The tablets and capsules require that many doses be administered throughout the day, which is generally not amenable to consumers, and particularly to diabetics and arthritics, who are typically already required to follow a regimen of medications in pill and capsule form and would be reluctant to add additional pills to their daily intake. Moreover, the powders require the consumer to prepare his own dose, which requires extra work on behalf of the consumer and allows for error in dosing.

The present invention overcomes the foregoing limitations by providing compositions comprising one or more chondroprotective agents in a convenient, stable, ready-to-drink form, which not only increases compliance through improved taste and convenience, but also is well suited for those in need of a decreased caloric and / or sugar intake *[page 2, lines 16-19]*.

More specifically, the present invention relates to: a beverage composition comprising: (a) a chondroprotective agent selected from the group consisting of cartilage, aminosugars, glycosaminoglycans, methylsulfonylmethane, S-adenosylmethionine, and mixtures thereof; (b) a sweetening agent selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, malitol, maltose, lactose, fructooligosaccharides, lo han guo, stevioside, acesulfame, sucralose, saccharin, xylose, arabinose, levulose, isomalt, ribose and mixtures thereof ; (c) at least about 75% water, by weight of the composition ; and (d) less than about 18 grams total carbohydrate per every 230 milliliters of the composition *[Claim 1]*. In particular, the aminosugars are selected from the group consisting of glucosamine and salts thereof; and the glycosaminoglycans are selected from the group consisting of chondroitin and salts thereof *[Claim 4]*. The beverage compositions further comprise

one or more beverage components selected from the group consisting of fruit juice, tea, milk solids, and mixtures thereof [*Claim 9*]. Additionally, the beverage compositions comprise one or more nutrients and /or one or more omega-3-fatty acids [*Claims 11-12*].

Finally, the present invention relates to a kit comprising: (a) a chondroprotective beverage composition as described above; and (b) information that administration of the composition to mammals, including those with diabetes, promotes joint health, bone health, and anti-inflammation of the joints [*Claim 43*].

PREVIOUS ISSUES

Is Claim 43 an improper process claim, and therefore, unpatentable under 35 U.S.C. § 101?

Do Claims 1, 2, 4, 7-9, 11, 12 and 43 contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, thus making the claims unpatentable under 35 U.S.C. §112, first paragraph?

Are Claims 1, 2, 4, 7-9, 11, 12 and 43 obvious over 20 prior art references cited by the Examiner under 35 U.S.C. § 103 (a)?

GROUPING OF CLAIMS

Claims 1-12 (herein “Group A”) are directed to the composition and thus, stand or fall together. Claim 43 (herein “Group B”) is directed to a kit, and is therefore, separately patentable.

PREVIOUS ARGUMENTS

The Rejection under 35 U.S.C. § 101

The Examiner asserts that Claim 43 is an improper process claim under 35 U.S.C. § 101 because of its alleged recitation of a use without setting forth any steps involved in the process. Appellants respectfully traverse this characterization and rejection.

First, Appellants respectfully assert that Claim 43 teaches a kit rather than a process. In 35 U.S.C. § 100, a “process” is defined as a “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material,” while a “kit” is a group of interrelated parts. See *In re Venezia*, 530 F.2d 956 (C.C.P.A. 1976). The present Claim 43 teaches a kit comprising the composition of Claim 1 along with information that administration of the composition to mammals, including those with diabetes, promotes joint health, bone health, and anti-inflammation of joints. Kit claims, such as the two-component kit claim presently at issue, are properly used for defining an invention. See *In re Venezia*, 530 F.2d 956 (C.C.P.A. 1976). Appellants

respectfully assert that, for the foregoing reasons, Claim 43 is a kit rather than a process, and as such, is properly patentable under 35 U.S.C. § 101.

Second, Appellants respectfully assert that because Claim 43 is a proper kit claim, and depends from Claim 1, which is itself patentable, Claim 43 is also patentable under 35 U.S.C. § 101. Moreover, Claim 43 incorporates information regarding the benefits of administration, thus providing a further limitation to an already allowable claim.

Finally, in the Final Office Action, the Examiner suggested the substitution of the word ‘administration’ for the word ‘use’ in Claim 43 ‘to overcome the instant grounds of rejection’ under 35 U.S.C. § 101. Appellants amended Claim 43 as suggested by the Examiner and as such, respectfully assert that Claim 43 is patentable under 35 U.S.C. § 101.

For the foregoing reasons, Appellants respectfully assert that Claim 43 is patentable under 35 U.S.C. § 101.

The Rejection under 35 U.S.C. § 112

A. Examiner’s Rejection

The Examiner has rejected claims 1, 2, 4, 7-9, 11, 12 and 43 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner objected to the use of the terms “cartilage,” “aminosugars,” and “glycosaminoglycans” in Claim 1, from which all other pending claims depend. More specifically, the Examiner states that the foregoing terms are “directed to a vast array of compounds, only a few of which are known to have the desired beneficial effects claimed.” Appellants respectfully traverse this rejection.

B. The Argument

Applicants concede that these terms encompass several chemical species, and acknowledge that it is possible that some of these individual species may provide better efficacy than others. However, Applicants respectfully assert that it does not follow that there exist species that provide absolutely no benefit whatsoever. These groups were selected by the Appellants based on scientifically sound observation, experiments and theory. In the previous response, Applicants requested the Examiner supply support for this rejection in the form of published data proving the lack of efficacy for specific chemical species within the claimed families. As this request has gone unanswered, Applicants respectfully request this rejection be reconsidered and withdrawn.

Moreover, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims, then the enablement requirement of § 112 is satisfied. *In re Fisher*, 427 F.2d 833

(CCPA 1970). Additionally, it is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. *In re Wertheim*, 541 F.2d 257 (CCPA 1976). Applicants respectfully assert that the present specification satisfies these requirements by clearly defining the aforementioned terms in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, at page 9, lines 9-24, a definition is provided that defines the term “cartilage” as “tough elastic tissue present in the joints (as well as other locations) of the bodies of various mammals. Cartilage is comprised of at least one of calcium, proteins, carbohydrate mucopolysaccharides, or collagen.” Moreover, examples are provided that suggest the preferred use of bovine cartilage and shark cartilage, as well as dosage requirements.

Similarly, page 9, line 25 through page 10, line 21, defines “aminosugar” as “monosaccharide components which are modified with an amine functionality.” Particularly preferred aminosugars include glucosamine, galactosamine, mannosamine, and the respective salts and N-acetyl derivatives thereof. Furthermore, examples are provided explaining the preferred use of glucosamine, as well as suggested dosage requirements.

Finally, cited prior art reference WO 98/48816 (November 5, 1998) issued to Henderson, and assigned to Nutramax Laboratories, defines “glycosaminoglycans” as “long chains composed of repeating disaccharide units of monosaccharides (aminosugar-acidic sugar repeating units), wherein the aminosugar is typically glucosamine or galactosamine.” Additionally, the present specification provides for the use of preferred glycosaminoglycans, including chondroitin, hyaluronic acid, keratan, heparin, dermatin, and salts of the foregoing, as well as providing dosage information. Furthermore, page 10, line 22 through page 11, line 10, defines glycosaminoglycans as “precursors to joint structure” and may be important for “the healing of bone.”

Taken as a whole, such definitions, preferred examples and dosage requirements, found in both the present application and the cited prior art, clearly provide enough information to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Therefore, Applicants respectfully assert that the specification of the present invention, in light of the information provided in the cited prior art references, satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph.

The Rejection under 35 U.S.C. § 103

The Examiner has rejected Claims 1, 2, 4, 7-9, 11, 12 and 43 under 35 U.S.C. § 103 as allegedly being obvious in light of 20 prior art references cited by the Examiner. Specifically, the Examiner asserts that the present invention is unpatentable over any one of the following references,

either alone or in combination: Rovati, U.S. Patent 3,683,076 (herein “Rovati 1”); Rovati, U.S. Patent 3,697,652 (herein “Rovati 2”); Herschler, U.S. Patent 4,296,130 (herein “Herschler 1”); Schinitzky, U.S. Patent 4,473,551 (herein “Schinitzky”); Herschler, U.S. Patent 4,616,039 (herein “Herschler 2”); Meisner, U.S. Patent 4,647,453 (herein “Meisner”); Herschler, U.S. Patent 5,071,878 (herein “Herschler 3”); Noel, U.S. Patent 5,141,964 (herein “Noel”); Henderson, U.S. Patent 5,587,363 (herein “Henderson 1”); Diaz, U.S. Patent 5,795,576 (herein “Diaz”); Murad, U.S. Patent 5,804,594 (herein “Murad”); Florio, U.S. Patent 5,840,715 (herein “Florio”); Burger, U.S. Patent 5,843,919 (herein “Burger”); Giampapa, U.S. Patent 5,895,652 (herein “Giampapa”); Henderson, U.S. Patent 5,364,845 (herein “Henderson 2”); Horrobin, WO 98/52556 (herein “Horrobin”); Henderson, WO 98/48816 (herein “Henderson 3”); Tapadinhas et al., “Oral Glucosamine Sulphate in the Management of Arthrosis: Report on a Multi-centre Open Investigation in Portugal,” *Pharmatherapeutica*, 3(3), 157-168 (1982) (herein “Tapadinhas”); Nakazawa et al., “The Therapeutic Effect of Chondroitin Polysulphate in Elderly Artherosclerotic Patients,” *Journal of Internal Medical Research*, 6, 217-225 (1978) (herein “Nakazawa”); and Vajradul “Double-Blind Clinical Evaluation of Intra-Articular Glucosamine in Outpatients with Gonarthrosis,” *Clinical Therapeutics*, 3(5), 336-343 (1981) (herein “Vajradul”). Moreover, the Examiner appears to cite the “vitamin shelf at Wal-Mart” (Final Office Action, pg. 9) as evidence of obviousness. Unless the Examiner provides examples of specific products, including their detailed composition and the date they were first made available to the public, the Appellants will consider this statement to be a mere editorial comment by the Examiner and not an actual rejection. As such, this comment will not be addressed further. Appellants respectfully traverse the rejection under 35 U.S.C. § 103.

A. Examiner’s Rejection

Absent reference to *any* specific passages in the 20 different references cited against the present claims, the Examiner asserts that because “the ingredients listed as actives are repeatedly disclosed as being known in the art as appropriate constituents of joint assisting food compositions...the instant claimed compositions, [and] kits thereof, are deemed to lack patentable distinction as being nothing more than a mixture of substance known in the prior art and therefore obvious.” While reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention, Appellants respectfully point out that a statement of rejection that includes a large number of rejections must explain with reasonable specificity at least one rejection, otherwise the Examiner procedurally fails to establish a *prima facie* case of obviousness. See *In re Gorman*, 933 F.2d 982 (Fed. Cir. 1991); See also *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989). In addition to the procedural deficiencies, generally citing a

voluminous number of references without specifically pointing out their relevance requires Appellants to presume the Examiner's motives. Henceforth, all references to the Examiner's "reliance" on the prior art are mere supposition.

B. The Prior Art

The Examiner presumably relies on 14 of the prior art references (herein "Chondroprotective Art") for the general teaching of chondroprotective compositions useful for treating joint and bone dysfunction, such as arthritis, osteoarthritis and arthrosis. More specifically, Rovati 1 teaches powders, tablets, capsules, injections and suppositories containing glucosamine sulfate and glucosamine hydroiodide for the general treatment of arthritic disease.

Rovati 2 teaches N-acyl aminocarbohydrates for oral, anal or injectable administration, to treat degenerative afflictions of the joints. The Rovati 2 compositions are preferably injectable aqueous solutions, in which the active constituent is associated with a carrier such as, for example, lactose, dextrose, sucrose, cocoa butter or water. While an injectable form is preferred, Rovati 2 also teaches tablets, capsules, suppositories, coated pills, solutions or the like.

Schinitsky teaches the use of cartilage, from shark, cattle, chicken, poultry and the like, along with glucosamine, for the treatment of such inflammatory conditions as arthritis, psoriasis and acne. Schinitsky discloses ointments, creams, lotions or injectable suspensions.

Meisner teaches oral administration of aminosugars, preferably a glucosamine salt, in conjunction with calcium, ascorbic acid and epinephrine, for the treatment of osteoarthritis or periodontal inflammation. For treating osteoarthritis, tablets, capsules and powders are preferred, while powders, pastes or gels are used to treat periodontal disease.

Henderson 1 discloses the oral dosage of glycosaminoglycans, preferably chondroitin and salts thereof, and aminosugars, preferably glucosamine and salts thereof, for the treatment and repair of connective tissue. Such compositions are capsules, tablets or powders mixed with animal feed.

Florio teaches the use of dietary supplements, for relief from arthritis consisting of gamma linolenic acid, a mixture of eicosapentaenoic and docosahexaneoic acids, and a mixture of chondroitin sulfate, N-acetylglicosamine sulfate, glucosamine sulfate and manganese aspartate. Florio also discusses the beneficial effects of methionine, glycosaminoglycans, superoxide dismutase, and various vitamins on arthritic disease.

Burger teaches a composition and a method of treating arthritis with glucosamine and omega-3-fatty acids in the form of tablets, capsules, pastes, gels, elixirs (given by teaspoonful), lozenges, sprays, suppositories, drops, patches, implants and oral or injectable solutions or suspensions. Additionally, the compositions include vitamin E.

Horrobin discloses compositions of glucosamine and an essential fatty acid for the treatment of arthritis and osteoarthritis. Such compositions may be applied by oral, enteral, parenteral or topical routes, and may be liquids, emulsions, powders, tablets or capsules.

Henderson 2 teaches the use of aminosugars, glycosaminoglycans and S-adenosylmethionine for repair of connective tissue. Manganese and Vitamin C are also disclosed as essential to the synergistic effect of the composition, the administration of which is via oral capsules.

Henderson 3 generally teaches a compositions for protection, treatment and repair, and for reducing the inflammation of connective tissue in humans and animals, consisting of various combinations of the following components via oral suspensions, elixirs, solutions, tablets, capsules, injection, or sublingual, nasal, guttural, rectal, transdermal or parenteral administration: aminosugars, preferably glucosamine, glucosamine hydrochloride, galactosamine, N-acetylglucosamine, and salts thereof; S-Adenosylmethionine; and a glycosaminoglycan, or glycosaminoglycan-like compound, preferably chondroitin or salts thereof, hyaluronic acid, glucaronic acid, iduronic acid, keratan sulfate, keratin sulfate, heparan sulfate, dermatin sulfate, pentosan polysulfate, and the like. Additionally, the compositions may include manganese and /or vitamins.

Tapadinhas presents the results of a clinical study in which the effectiveness and tolerability of oral glucosamine sulfate was evaluated. It was determined that oral glucosamine sulfate, administered in capsule form, was useful in the treatment of arthrosis.

Nakazawa presents the findings of a clinical study investigating the effects chondroitin polysulfate in treating elderly atherosclerotic patients. The study was inconclusive as to the role CPS plays in these degenerative diseases, and the mechanism by which it functions. Further investigation was deemed necessary.

Vajaradul describes a clinical study investigating the use of intra-articular injections of glucosamine in treating gonarthrosis. Specifically, the study tested a glucosamine preparation thought to reduce or even stop degeneration, and rebuild damaged articular cartilage. The results of the study indicate that glucosamine is useful in relieving the pain associated with arthrosis. Intramuscular and oral administrations were also found to be effective, with intramuscular treatment preferably reserved for generalized arthrosis, and oral administration preferred as a follow-up of intra-articular treatment.

Finally, Herschler 2 teaches methylsulfonylmethane in dietary products to correct sulfur-deficient diets and thereby, treat physiological conditions, such as arthritis. Herschler 2 discloses incorporating methylsulfonylmethane into such things as processed foodstuffs, beverages, supplements, confectionary products and chewing gum.

While the foregoing references arguably teach the use of chondroprotective compositions, such as aminosugars, glycosaminoglycans and methylsulfonylmethane, to treat various forms of arthritis and

other physiological conditions, none of the Chondroprotective Art references, either alone or in combination, teaches several important components of the present invention. Namely, the prior art fails to discuss the water content, which is crucial since the present invention teaches beverages; low carbohydrate content, which is important to the present invention because it is directed towards diabetics and those generally concerned with sugar intake; or the various vitamins and minerals contained in the present invention. Moreover, the prior art fails to teach the kits of the present invention, which are important in informing consumers regarding the benefits of the present invention.

To address some of these important deficiencies, the Examiner appears to rely on 3 additional prior art references, Herschler 1, Noel and Murad, (herein "Cosmetic Art"), which generally teach cosmetic chondroprotective compositions useful for treating skin conditions and /or maintaining the health of the skin and nails.

More specifically, the Examiner appears to rely on Herschler 1 for the general teaching of methylsulfonylmethane compositions, preferably in the form of lotions, creams or gels, useful in conditioning the skin and nails. Herschler 1 also discloses methylsulfonylmethane administered orally, as an injection, or via inhalation, useful as a diluent for the blood. Finally, Herschler 1 teaches methylsulfonylmethane-containing syrups, tablets and capsules, which aid in preserving pliancy of the intestines and other tissues.

Noel generally teaches creams, toners, emulsions and liquid soaps containing glucosamine, chitosan and at least one of succinic acid and gluconic acid, which moisturize and improve the condition of the skin.

Murad generally teaches glycosaminoglycans, along with antioxidants, amino acids and a transition metal to prevent and treat skin conditions by modifying the thickness of the skin. Optionally, the compositions in Murad may also contain glucosamine and salts thereof, chondroitin and vitamins. The compositions may be oral, topical, rectal, parenteral, intravenous or injectable, and may include tablets, capsules, dispersions, suspensions, patches or solutions.

Finally, the Examiner appears to rely on 3 remaining prior art references, (herein "Miscellaneous Art") presumably for the general teaching of further components of the present invention.

More specifically, Herschler 3 generally teaches the use of methylsulfonylmethane to correct sulfur-deficient diets in mammals, and particularly, human beings. This supplementation is accomplished by adding the methylsulfonylmethane to the foodstuff regularly consumed by the mammals.

Diaz generally teaches dietary capsules which aid in the absorption, binding and elimination of undigested fat, comprising a fibrous agent, such as psyllium, along with glucosamine hydrochloride, glucomannan, apple pectin and stearic acid.

Giampapa generally teaches oral supplements taken three times daily, that aid in maintaining body function in an effort to counter the effects of aging. The supplements disclosed in Giampapa contain such components as antioxidants, vitamins, minerals, amino acids and omega-3 oils.

In spite of this extensive list, Appellants respectfully assert that the prior art, either alone or in combination, fails to address some of the key aspects of the present invention, thus, making it unobvious under 35 U.S.C. § 103. These deficiencies are discussed in greater detail below.

C. The Argument

Under existing law, any person who “invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. §101. Under the various sections of the 1952 Patent Act, as amended and interpreted, the Applicant is *entitled* to a patent unless the examiner can show, among other things not presently at issue, obviousness.

In particular, the Examiner bears the burden of factually supporting any *prima facie* conclusion of obviousness. In determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fe. Cir. 1983). Distilling the invention down to the “gist” or “thrust” of an invention disregards the requirement of analyzing the subject matter “as a whole.” See *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). If, viewing the invention as a whole, the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of non-obviousness. See *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). In other words, under current law, Applicants are not initially required to make any special showing of new, unexpected, or useful function to be considered patentable. Inventors of unobvious compositions, such as those of the present invention, enjoy a *presumption* of non-obviousness, which must then be overcome by the Examiner establishing a case of *prima facie* obviousness by the appropriate standard. If the Examiner does not prove a *prima facie* case of unpatentability, then without more, the Applicant is entitled to grant of the patent. See *In re Oetiker*, 977 F.2d 1443.

As aforementioned, the Examiner’s generalization that the invention is known in the art without any specific passages referenced, does not meet the Examiner’s burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness under 35 U.S.C. §103, the Examiner must meet three basic criteria. First, there must be some suggestion or

motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest *all* the claim limitations. See, for example, *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Appellants respectfully assert that the Examiner fails to establish the first and third criteria, and thus, fails to establish a *prima facie* case of obviousness.

1) Group A Claims

First, Appellants respectfully assert that there is no motivation for one skilled in the art to modify the references or combine reference teachings. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). Moreover, when the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the Examiner to explain why the combination of the teachings is proper. See *Ex parte Skinner*, 2 USPQ 2d 1788 (Brd. Pat. App. & Inter. 1986). While the references cited by the Examiner arguably teach some individual components of the present invention, Appellants respectfully assert that the present invention is more than a list of ingredients and the skilled artisan would not be motivated to modify or combine these teachings in such a way as to achieve the present invention.

More specifically, the Chondroprotective Art arguably discloses the use of amino sugars, glycosaminoglycans and methylsulfonylmethane to treat arthritis, osteoarthritis, and other degenerative joint and bone diseases. However, in order to overcome the stability issues traditionally associated with such agents, the chondroprotective compositions of the prior art are most frequently prepared as capsules, tablets, powders, suppositories, elixirs and syrups. Appellants respectfully assert that there is nothing in the Chondroprotective Art that suggests the desirability of the present invention, which teaches ready-to-drink chondroprotective beverage compositions that overcome the known formulation difficulties. There is no motivation in the prior art that teaches or suggests the beverage compositions of the present invention.

Additionally, the present invention teaches low-calorie compositions favorable for individuals who are diabetic, overweight, obese, or generally concerned about caloric or sugar intake. It is well known that glucosamine itself has an unpleasant taste. In order to make glucosamine products more amenable to consumers, one skilled in the art might be inclined to add sugary flavoring agents to mask the unpleasant taste. Such high sugar content would render these products unavailable to the individuals targeted by the present invention who need or desire a low-calorie alternative. Thus, Appellants respectfully assert that the prior art fails to provide the motivation necessary to

produce a low-calorie chondroprotective beverage since it is well known that sugary, high calorie flavoring agents must be added to cover-up the unpleasant taste.

Together, these key features make the present invention a vast improvement over the prior art by providing a ready-to drink, low-calorie chondroprotective beverage, in a convenient form, for individuals who are overweight, obese, diabetic, or generally concerned with caloric intake - individuals who have been overlooked by the products of the prior art. Additionally, the pleasant taste of the present invention helps drive compliance by ensuring consumers adhere to their daily.

Moreover, the teachings of the Cosmetic Art and the Miscellaneous Art do little to remedy the foregoing deficiencies. In general, the Cosmetic Art discloses the use of methylsulfonylmethane or glucosamine to treat various conditions of the skin and nails, while the Miscellaneous Art discloses the use of these chondroprotective agents to correct diet deficiencies and to bind and eliminate fat. While one Miscellaneous Art reference arguably teaches the use of vitamins, minerals and omega-3-fatty-acids to counter aging, this alone still does not suggest the desirability of modifying or combining reference teachings to obtain the present invention. Thus, Appellants respectfully assert that the motivation to modify or combine references is not immediately apparent, and as such, the burden of identifying the motivation lies with the Examiner. By generally citing 20 references, Appellants respectfully assert that the Examiner has failed to meet this burden.

Second, the prior art references, alone or in combination, do not teach or suggest *all* the claim limitations. Assuming *arguendo* that one skilled in the art would be motivated to modify or combine the cited references in the first instance, Appellants respectfully assert that there remain key components of the present invention that the prior art fails to address. Neither the Chondroprotective Art, the Cosmetic Art, nor the Miscellaneous Art addresses the limitations requiring the composition to be a beverage and to be low-calorie. As aforementioned, these two factors are key to the present invention in that they represent significant improvement over the prior art. In failing to teach these features, the prior art fails to teach all of the claim limitations of the present invention.

Thus, the prior art lacks the necessary motivation for one skilled in the art to modify or combine reference teachings. Moreover, the prior art references, alone or in combination, fail to teach or suggest *all* the claim limitations. Therefore, Appellants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103 in regards to the Group A Claims. As such, withdrawal of the rejection is respectfully requested.

Additionally, it is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. See *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). Appellants respectfully submit that the Examiner has used impermissible hindsight to selectively

“pick and choose” necessary components from the prior art in order to conclude that the Group A Claims are obvious, when in fact, there is no motivation or suggestion to do so. Such manipulation of the prior art is improper and thus, for this further reason, Appellants respectfully assert that the rejection under 35 U.S.C. § 103 must be withdrawn.

2) Group B Claim

Appellants assert that all of the foregoing arguments relating to the Group A Claims apply equally to the Group B Claim since the Group B Claim depends from a member of the Group A Claims. Additionally, Appellants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to the Group B Claim for the following reasons.

First, Appellants respectfully assert that there is no motivation for one skilled in the art to modify the references or combine reference teachings. The teaching or suggestion to modify or combine reference teachings, and the expectation of success, must be found in the prior art, and may not be based on Applicants’ disclosure. See *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Neither the Chondroprotective Art, the Cosmetic Art, nor the Miscellaneous Art teaches or suggests the use of kits to inform consumers of the benefits and uses of the disclosed products. Appellants respectfully assert that the Examiner has in fact used the Appellants’ own disclosure to find the requisite motivation needed to declare such kits obvious. As this is an improper source for obviousness determination purposes, Appellants respectfully assert that the first requirement for establishing a *prima facie* case of obviousness has not been satisfied.

Second, the prior art references, alone or in combination, do not teach or suggest *all* the claim limitations. As aforementioned, none of the cited prior art teaches or suggests the use of kits to inform consumers of the benefits of the disclosed products. As such, Appellants respectfully assert that the requirement that all claim limitation must be taught has not been satisfied, and thus the third factor for establishing a *prima facie* case has not been met.

Based upon this absence of “kits” in the cited prior art, Appellants respectfully assert that the Examiner actually relies on 35 U.S.C. § 112 as the basis of the rejection of the Group B Claim and not 35 U.S.C. § 103. Therefore, Appellants respectfully assert that the rejection under 35 U.S.C. § 103 is improper and must be withdrawn.

Findings of fact relied upon in making the obviousness rejection must be supported by substantial evidence within the record. See *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). Appellants respectfully assert that, for all of the above reasons, the Examiner has failed to support the obviousness rejection with substantial evidence, and thus, has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103. Therefore, Appellants respectfully request the rejection of Claims 1, 2, 4, 7, 8, 9, 11, 12 and 43 be withdrawn.

CONCLUSION

It is respectfully submitted that the Examiner's rejection of Claim 43 under 35 U.S.C. § 101, and Claims 1, 2, 4, 7-9, 11, 12 and 43, under 35 U.S.C. § 112 and 35 U.S.C. § 103 in view of 20 cited references, without more, is improper. Reversal of such rejections is therefore respectfully requested.

Respectfully submitted,
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Date: August 3, 2004
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APPENDIX

1. A beverage composition comprising;

- (a) a chondroprotective agent selected from the group consisting of cartilage, aminosugars, glycosaminoglycans, methylsulfonylmethane, S-adenosylmethionine, and mixtures thereof;
- (b) a sweetening agent selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, malitol, maltose, lactose, fructooligosaccharides, lo han guo, stevioside, acesulfame, sucralose, saccharin, xylose, arabinose, levulose, isomalt, ribose and mixtures thereof;
- (c) at least about 75% water, by weight of the composition; and
- (d) less than about 18 grams total carbohydrate per every 230 milliliters of the composition.

2. A composition according to Claim 1 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, S-adenosylmethionine, and mixtures thereof.

[Claim 3 has been cancelled]

4. A composition according to Claim 2 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, S-adenosylmethionine, and mixtures thereof and wherein:

- (a) the aminosugars are selected from the group consisting of glucosamine and salts thereof; and
- (b) the glycosaminoglycans are selected from the group consisting of chondroitin and salts thereof.

[Claims 5 and 6 have been cancelled]

7. A composition according to Claim 4 wherein the sweetening agent is selected from the group consisting of xylitol, erythritol, fructooligosaccharides, lo han guo, stevioside, acesulfame, sucralose, and mixtures thereof.
8. A composition according to Claim 7 wherein the sweetening agent is selected from the group consisting of erythritol, sucralose, and mixtures thereof.
9. A composition according to Claim 8 further comprising one or more beverage components selected from the group consisting of fruit juice, tea, milk solids, and mixtures thereof.

[Claim 10 has been cancelled]

11. A composition according to Claim 9 further comprising one or more nutrients.
12. A composition according to Claim 9 further comprising one or more omega-3-fatty acids.

[Claims 13-42 have been cancelled]

43. A kit comprising:
 - (a) a composition according to Claim 1; and
 - (b) information that administration of the composition to mammals, including those with diabetes, promotes joint health, bone health, and anti-inflammation of joints.

[Claims 44-50 have been cancelled]